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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,370	01/22/2004	David Wallach	WALLACH=27A	3756
1444 7590 04/29/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER POPA, ILEANA	
			ART UNIT 1633	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/761,370	<b>Applicant(s)</b> WALLACH ET AL.	
	<b>Examiner</b> ILEANA POPA	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

1. Claims 2-16 have been cancelled. Claims 20-23 are new.  
Claims 1 and 17-23 are pending and under examination.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

2. Claims 1 and 17-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yongan (PhD thesis, published in OCLC's Experimental Thesis Catalog and also issued on microfilm in 1966; Abstract), in view of both Yongan et al. (Mol Cell Biol, March 1<sup>st</sup>, 1998, 18: 1601-1610) and Ellis et al. (J Immunol, 1995, 155: 925-937) for the reasons of record set forth in the non-final Office action of 07/26/2007. Applicant's arguments filed 01/28/2008 have been fully considered but they are not persuasive.

Applicant traversed the instant rejection on the grounds that the cited and applied references, as well as the prior art, do not teach any antibodies against FIP-2. Applicant argues that, although the Examiner takes the position that it would be obvious to make such antibodies against FIP-2, the vast majority of monoclonal antibodies raised against FIP-2 would not bind to RAP-2 because the areas of overlap (sequence identity) are small (it is noted that Applicant argues that there is only 57% identity between the 30 amino acids long C-terminal domains of RAP-2 and FIP-2 and that the assertion of virtual identity between these domains is incorrect). Applicant argues that

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antibodies against FIP-2 that can also bind RAP-2 would have the unexpected property of also binding to RAP-2 and that this unexpected property cannot be anticipated by anti-FIP-2 antibodies in general, even if they were taught in the prior art, which they are not. Applicant submits that the presence of the property of also binding to RAP-2, which clearly would be unexpected, rebuts any holding of prima facie obviousness.

Additionally, Applicant points out that claim 1 is now amended to clarify that the antibody is specific for RAP-2, as supported by the present specification. Applicant submits that paragraphs 0054 and 0168 disclose that the claimed antibodies are specific for RAP-2, i.e., are unique to RAP-2 protein and not directed to epitopes common with other proteins; Applicant points out that one of skill in the art would recognize that an antibody specific for RAP-2 would recognize only RAP-2 in the presence of other proteins, i.e., in the presence of FIP-2. Therefore, Applicant submits that specific for RAP-2 implicitly means that the antibody is specific for a RAP-2 epitope not found in other proteins, including FIP-2. Therefore, Applicant requests the withdrawal of the rejection.

Applicant's arguments are acknowledged, however, the rejection is maintained for the following reasons:

The argument that the cited art does not teach anti-FIP-2 antibodies is not found persuasive because, as indicated in the non-final Office action of 07/26/2007, it would have been obvious to one of skill in the art to raise such antibodies. The argument that the overlapping regions are small and therefore the vast majority of monoclonal antibodies raised against FIP-2 would not bind to RAP-2 is irrelevant. The instant

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claims are broadly drawn to any antibody specific for RAP-2, and therefore, they encompass antibodies against the overlapping regions; the combined teachings of the references cited above disclose such an antibody and therefore renders the claimed invention *prima facie* obvious. With respect to the argument of only 57% identity, it is noted that the instant specification teaches that "the homology however becomes more significant in specific regions towards the C-terminus of the proteins, culminating with virtual identity of the 30 C-terminal amino acids" (paragraph 0019). Therefore, the statement of "virtual identity" used by the Examiner is not incorrect. The argument of unexpected results is not found persuasive because, since the FIP-2 leucine zipper domain and RAP-2 C-terminus are conserved, binding to RAP-2 is an inherent property of an antibody directed against FIP-2 leucine zipper. There is nothing unexpected about it. The argument that the claimed specific antibodies are unique to RAP-2 protein and not directed to epitopes common with other proteins is not found persuasive. Applicant submits that the definition of "specific" or "specificity" of an antibody in Cruse and Lewis' "Illustrated Dictionary of Immunology", 1995, CRC Press, New York, (pertinent pages submitted with the response), is the recognition of a specific epitope in the presence of other epitopes. Applicant argues that, based on such a definition, one of skill in the art would immediately recognize and understand that antibodies specific for RAP-2 would recognize only RAP-2 in the presence of other proteins, i.e., in the presence of FIP-2 as well. Cruse and Lewis define "specific" and "specificity" as follows:

**specific immunity**

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An immune state in which antibody or specifically sensitized primed lymphocyte recognize an antigen and react with it.

**specificity**

Recognition by an antibody or lymphocyte receptor of a specific epitope in the presence of other epitopes for which the antigen-binding site of the antibody or of the lymphoid cell receptor is specific.

According to these definitions a specific antibody recognizes a specific epitope in the presence of other epitopes, which other epitopes can be from the same antigen or different antigens; one of skill in the art would that a monoclonal antibody specific for an epitope could bind two different antigens if the specific epitope is present in both antigens; for example, a monoclonal antibody specific for an epitope within the last 12 amino acids of FIP-2 would also be specific for RAP-2 because the last 12 C-terminal amino acids of FIP-2 and RAP-2 are identical, and therefore, RAP-2 would necessarily comprise the specific epitope to which the antibody is directed; it is noted that both proteins comprise multiple epitopes and, since the monoclonal antibody only binds the specific epitope within the last 12 amino acids and does not bind the other epitopes, it does bind the specific epitope in the presence of other epitopes. One of skill in the art would readily recognize that a monoclonal antibody as mentioned above would recognize both FIP-2 and RAP-2. For all these reasons, the rejection is maintained.

***New Rejections******Claim Rejections - 35 USC § 112, first paragraph, new matter***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the amendment to the claim to exclude antibodies recognizing epitopes found in FIP-2 is considered new matter.

Applicants point to paragraphs 0054 and 0168 for support. Applicant argues that paragraphs 0054 and 0168 disclose that the claimed antibodies are specific for RAP-2, i.e., are unique to RAP-2 protein and not directed to epitopes common with other proteins; Applicant points out that one of skill in the art would recognize that an antibody specific for RAP-2 would recognize only RAP-2 in the presence of other proteins, i.e., in the presence of FIP-2. Therefore, Applicant submits that specific for RAP-2 implicitly means that the antibody is specific for a RAP-2 epitope not found in other proteins, including FIP-2.

The mere recitation of an antibody specific for RAP-2 is not considered support for specifically excluding antibodies directed to epitopes found in FIP-2 for the reasons set forth above.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02

teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633